Citation:

Raatz SK, Torkelson CJ, Redmon JB, Reck KP, Kwong CA, Swanson JE, Liu C, Thomas W, Bantle JP. Reduced glycemic index and glycemic load diets do not increase the effects of energy restriction on weight loss and insulin sensitivity in obese men and women. *J Nutr.* 2005 Oct; 135(10): 2,387-2,391.

PubMed ID: 16177201

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine whether a hypocaloric diet with reduced glycemic load and glycemic index would result in greater sustained weight loss and metabolic improvements in obese men and women.

Inclusion Criteria:

Healthy men and women ages 18 to 70 years with a body mass index (BMI) of 30 to 40kg/m^2 who habitually consumed a regular diet with no food restrictions.

Exclusion Criteria:

Taking prescription medication, had an existing medical condition or were pregnant.

Description of Study Protocol:

Recruitment

Subjects were recruited from the University of Minnesota and Minneapolis/St. Paul metropolitan communities.

Design

Three-arm parallel-design randomized 12-week controlled feeding trial with a 24-week follow-up phase.

Dietary Intake/Dietary Assessment Methodology

- Five-day food records were completed at week 24 and 36 during the free-living phase and

dietary glycemic index and load were calculated
- Subjects were asked to complete daily questionnaires throughout the feeding phase to report any dietary treatment deviations by recording any foods consumed in addition or omitted from the prescribed diet.

Intervention

- During weeks one to 12 (feeding phase), subjects consumed individualized energy-restricted diets to promote a weight loss of 0.70kg per week. All meals were prepared in a metabolic kitchen. Subjects were required to consume all food provided and no foods other than those provided
- During weeks 13 to 24 (free-living phase), diet assignment was maintained, but subjects prepared their own meals. Subjects were given intensive dietary instruction and had nutritional counseling every two weeks.
- The three hypocaloric diet arms varied in macronutrient content, glycemic index and glycemic load:
    - High-glycemic index diet: High glycemic load and index [60% carbohydrate, 15% protein, 25% fat, glycemic index = 63, glycemic load = 272, fiber = 9.1g per 4,184kJ]
    - Low-glycemic index diet: Low glycemic load and index [60% carbohydrate, 15% protein, 25% fat, glycemic index = 33, glycemic load = 178, fiber = 16.7g per 4,184kJ]
    - High-fat diet: Low glycemic load and high glycemic index [45% carbohydrate, 15% protein, 40% fat, glycemic index = 59, glycemic load = 182, fiber = 8.6g per 4,184kJ].

Statistical Analysis

- ANOVA with T-tests among group means was used for anthropometric and metabolic measurements
- Changes from baseline within treatment groups were compared by paired T-tests
- A P-value less than 0.05 was considered statistically significant and a P-value of 0.10 or less denoted a trend.

Data Collection Summary:

Timing of Measurements

- Anthropomorphic (body weight, height, body composition) and biochemical measurements (plasma glucose, triglycerides, serum insulin) were obtained at baseline and weeks four, eight, 12, 24 and 36
- Body weight was measured daily during the first 12 weeks
- Five-day food records were completed at weeks 24 and 36
- Mixed meal tolerance test was performed at week 12 and blood samples were analyzed for glucose, insulin and triglyceride concentrations.

Dependent Variables

- Body weight
- BMI
- Body composition (fat, lean mass): Sum of four skinfold measurements
- Serum insulin
- Plasma glucose
- Plasma triglycerides.

Independent Variables

- High-glycemic index diet
- Low-glycemic index diet
- Low-fat diet.

Description of Actual Data Sample:

- *Initial N:* 42
- *Attrition (final N):*
  - 29 subjects completed the 12-week feeding phase
  - 22 subjects completed the full 36-week trial
- *Anthropometrics:* At baseline, the high-fat diet group had significantly lower fasting triglycerides than the other two groups
- *Location:* Minnesota.

Summary of Results:

Change in Endpoint Measurements [Mean (SEM)] in Obese Men and Women Fed High-glycemic Index, Low-glycemic Index, and High-fat Diets from Baseline to Week 12 of the Feeding Phase

Variables	High-glycemic Index Diet N=9	High-fat Diet N=10	Low-glycemic Index Diet N=10
Weight (kg)	-9.3 (1.3)	-8.4 (1.5)	-9.95 (1.4)
Body mass index	-3.0 (0.4)	-3.0 (0.5)	-3.91 (0.5)
Body fat (percent)	-2.8 (0.7)	-2.5 (0.8)	-2.9 (0.4)
Fat (kg)	-4.5 (1.9)	-5.8 (1.0)	-6.9 (0.9)
Lean body mass (kg)	-4.8 (2.2)	-2.6 (1.0)	-3.04 (0.6)
Fasting serum insulin (pmol per L)	-20.1 (6.9)	-6.3 (4.8)	-28.5 (6.3)
Fasting plasma glucose (mmol per L)	-0.3 (0.1)	-0.2 (0.1)	-0.2 (0.1)
Fasting plasma triglycerides (mmol per L)	-0.5 (0.2)	0 (0.1)	-0.4 (0.3)

Other Findings

- Each diet group lost weight during the 12-week feeding phase ($P<0.001$), but the amount lost did not differ among the groups
- The high-fat and low-glycemic index groups maintained their lean body mass ($P=0.01$) at week 12
- The calculated HOMA values (insulin sensitivity) were significantly improved at week 12 compared with baseline in all groups ($P=0.03$). The improvement in the low glycemic index

group was significantly greater than the high fat group at week 12 (P<0.05)
- Plasma glucose or serum insulin responses to a mixed meal test did not differ among the groups at week 12
- The plasma triglyceride concentration was lower (P=0.02) in the high-fat group than in the other two groups at week 12
- Weight loss and improvements in HOMA scores achieved during the first 12 weeks were maintained in all three groups at week 36 and these values did not differ among the groups
- Based on the 18 subjects who completed five-day food records at 24 and 36 weeks, all three groups consumed diets of relatively low glycemic index and glycemic load during weeks 24 to 36. The glycemic indices of the diets differed at week 24 (P=0.014), with low glycemic index diet group consuming a lower glycemic index diet. By week 36, the diets did not differ in glycemic index. The low-glycemic index group chose lower glycemic index foods, but the other two groups simply increased dietary fat.

Author Conclusion:

- Energy restriction over a 36-week period promotes weight loss and improves insulin sensitivity in obese individuals, irrespective of diet substrate
- A reduced glycemic index and glycemic load diet did not enhance weight loss relative to the other diets.

Reviewer Comments:

Author-identified limitation: Loss of subjects during follow-up and no knowledge of why they dropped out.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes

1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	No
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes

4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes

7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes